IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Michael YEADON, et al. Examiner: Yong Soo Chong

Serial No.: 10/720,050 Group Art Unit: 1617

Filed: November 19, 2003 Confirmation No.: 3489

Title: COMBINATION OF A DOPAMINE D2-RECEPTOR AGONIST AND TIOTROPIUM OR A DERIVATIVE THEREOF FOR TREATING OBSTRUCTIVE AIRWAYS AND OTHER INFLAMMATORY DISEASES

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed June 21, 2007, applicants have the following elections. A Petition for a 1-Month Extension of Time is filed herewith.

The Restriction Requirement

In response to the restriction requirement, applicants hereby elect Group I-A, the compositions comprising a dopamine D2-receptor agonist and an anti-cholinergic according to formula (1.1.1). The election is made with traverse for the reasons set forth below. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter.

Initially, it is pointed out that the restricted Groups for election set out in the Office Action do not encompass the full scope of the claims. The Groups I-IV only relate to embodiments where the anti-cholinergic is of formula (1.1.1), however, the invention is not so restricted and the Groups for election do not encompass other embodiments using other anti-cholinergics; see, e.g., claims 6-10. Thus, the restriction is traversed for failure to consider the full claimed invention.

Additionally, applicants respectfully traverse the restriction among Groups IA-IW. The Office Action provides no basis whatsoever for restricting the single invention of the claimed compositions recited in claim 1 into 24 separate groups. No basis is even alleged to support restriction among the Groups A-W. Thus, the restriction among these Groups must be withdrawn.

In any event, restriction among Groups A-W is not supportable. Claim 1 is a proper Markush group. A Markush claim **can** contain independent and distinct inventions such that a prior art reference anticipating the claim with respect to one member would not render the claim obvious with respect to another member. The PTO's own rules on this matter set forth in M.P.E.P. §803.02 specifically state that:

> "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s)."

This section of the M.P.E.P. makes clear that such a claim is a proper Markush claim and should be examined in accordance with Markush practice. Furthermore, M.P.E.P. §2173.05(h) discusses types of improper Markush claims and applicants' claims are not of the type indicated to be improper therein. Accordingly, it is respectfully submitted that the instant claims are proper Markush claims and, therefore, restriction is not proper.

Applicants also traverse the restriction of Groups II-IV from Group I. Groups II-IV are directed to the method of use of the compositions of Group I. As the basis for restriction, the Office Action alleges that "another method of treating obstructive airway disease, such as asthma, is environmental management to avoid asthma triggers and an established drug regimen including bronchodilators." However, such allegation does not support restriction among composition and method of use claims. The fact that the condition can be treated by a different method does not meet one of the requirements for supporting restriction, i.e., (1) the process can be practiced with a materially different product, or (2) the product can be used in a materially different process. As for (1), using a different product would not result in the claimed method because there is no evidence to support that a different product would

provide the materially same effect. As for (2), there is no evidence to suggest the product can be used in a materially different process. The processes of Groups II-IV are within the same genus, i.e., treatment of obstructive airway other inflammatory diseases. Claim 12 is generic to each of the alleged Groups II-IV, which is why claims 13-19 are all ultimately dependent on claim 12. No proof or objective evidence is provided to support that the Groups II-IV are directed to materially different processes.

Further, it is not correct that the inventions of Group II-IV are "unrelated." Clearly they are related since each is within the genus of methods for treatment of obstructive airway other inflammatory diseases. A cursory review of the prior art in the field evidences the close relation between methods of treating asthma and COPD.

Accordingly, it is urged that the restriction of Groups II-IV from Group I and from each other is not supported on the record and should be withdrawn.

For all of the above reasons, it is urged that the restriction requirement should be withdrawn, in total.

The Election of Species Requirement

In response to the requirement for an election of species, applicants hereby elect pramipexole as the species of D2 receptor agonist. It is believed that claims 1-4, 6-10, 20-24 and 26-34 encompass the elected species.

The Examiner is encouraged to examine the broadest possible scope of invention indicated by the elected species. In accordance with M.P.E.P. §803.02, the Examiner is reminded that, should no prior art be found which renders the invention of the elected species unpatentable, the search of the remainder of the generic claim(s) should be continued in the same application. It is improper for the PTO to refuse to examine in one application the entire scope of the claims therein unless they lack unity of invention. The generic claims herein have not been alleged to lack unity of invention.

Favorable action is earnestly solicited.

No fee, other than the 1-Month Extension of Time being paid herewith, is believed to be due with this Amendment. However, the Commissioner is hereby authorized to charge

any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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